PATENT
32860-001019/US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANTS:	Kristine FUIMAONO et al.	CONF. NO.:	3067
APPL'N NO.:	10/569,957	GROUP:	3777
FILED:	November 30, 2006	EXAMINER:	Hien Nguyen
FOR:	METHOD AND DEVICE FOR VISUALLY SUPPORTING AN ELECTROPHYSIOLOGICAL USE OF A CATHETER IN THE HEART		

APPELLANTS' BRIEF ON APPEAL UNDER 37 C.F.R. § 41.37

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Sir/Madam:

Further to Appellants' Notice of Appeal filed December 16, 2010, and the Notice of Panel Decision mailed January 31, 2011, Appellants hereby submit their Brief on Appeal in accordance with 37 C.F.R. § 41.37.

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I. REAL PARTY IN INTEREST.

The real party in interest is Siemens Aktiengesellschaft.

II. RELATED APPEALS AND INTERFERENCES.

No related appeals or interferences are known.

III. STATUS OF CLAIMS.

Claims 1-3, 9-10, 14-15, 18 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,556,695 ("Packer") in view of U.S. Patent No. 6,128,002 ("Leiper"), U.S. Patent Appln. Pub. No. 2002/0176608 ("Rose") and *A System for Multimodality Image Fusion,* Seventh Annual IEEE Symposium on Computer-Based Medical Systems, 1994, pp. 335-340 ("Hemler").[1]

Claims 17, 21, and 6 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler and German Patent Application No. 19953308 ("Williams").[2]

Claims 23 and 13 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler and U.S. Patent No. 7,233,340 ("Hughes").[3]

Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler and U.S. Patent No. 6,144,875 ("Schweikard").[4]

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[1] Final Office Action, U.S. Appln. No. 10/569,957, U.S. Pat. and Trademark Office, p. 2 (September 16, 2010).
[2] Id. at 5.
[3] Id. at 6.

Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler and U.S. Patent No. 6,771,262 ("Krishnan").[5]

Claim 12 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Packer in view of Leiper and further in view of Rose, Hemler and U.S. Patent Appln. Pub. No. 2002/0087329 ("Massaro").[6]

Claims 4-5, 7, 16, 19-20 and 24-29 were cancelled in the Amendment filed on April 29, 2009.

Claims 1-3, 6, 8-15, 17-18 and 21-23 are being appealed.

IV. STATUS OF AMENDMENTS.

No amendments were filed subsequent to the September 16, 2010 Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER.

A. CONCISE EXPLANATION OF THE SUBJECT MATTER SET FORTH IN EACH CLAIM ARGUED SEPARATELY.

1. A GENERAL DISCUSSION OF THE SUBJECT MATTER DESCRIBED IN THE SPECIFICATION TO ASSIST THE BOARD IN UNDERSTANDING EXAMPLE EMBODIMENTS DESCRIBED IN THE PRESENT APPLICATION.

FIG. 1 illustrates the individual steps in the performance of the present method and individual modules of the associated device, according to a non-

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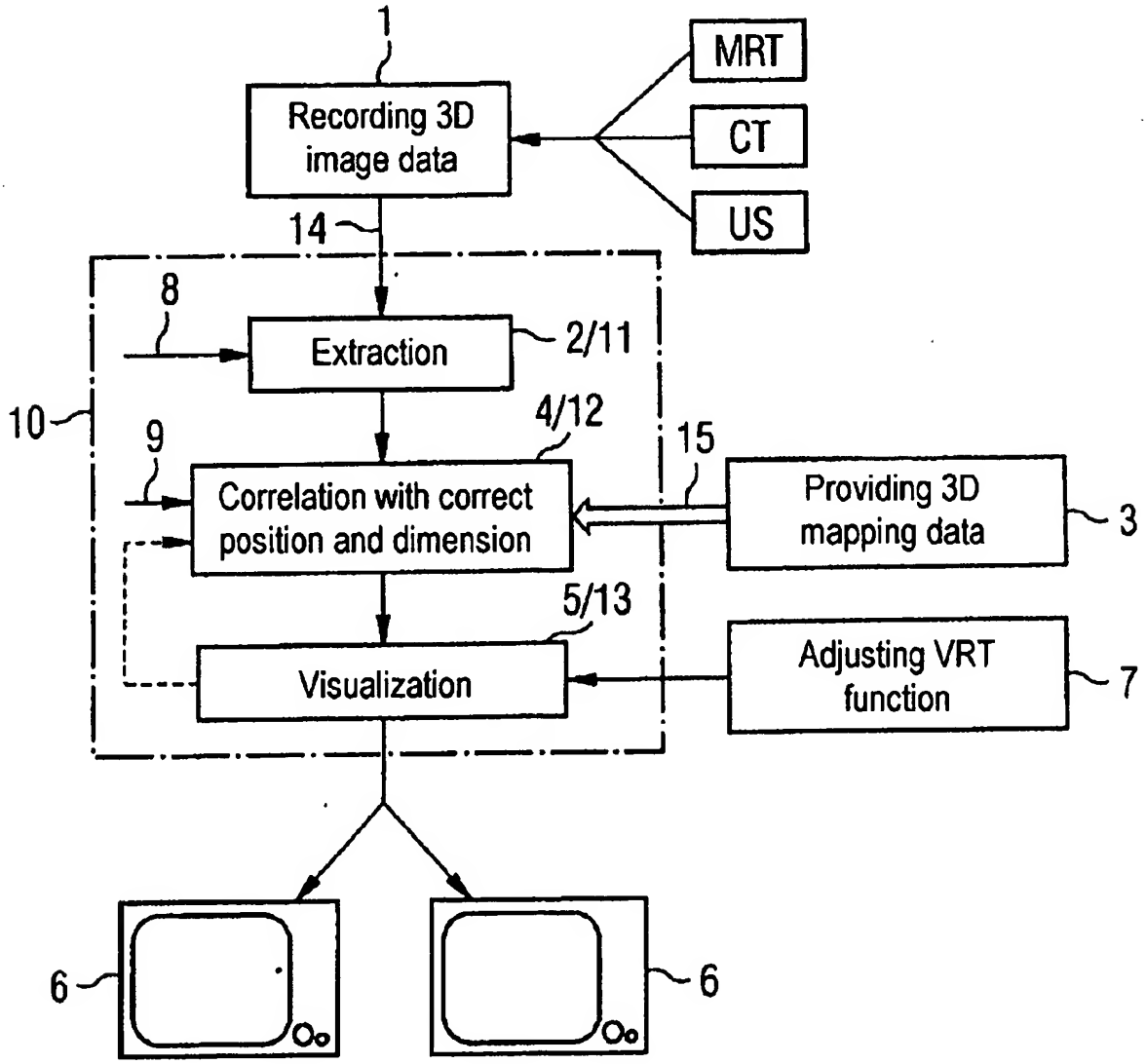
[4] Id. at 7.
[5] Id.
[6] Id. at 8.

limiting embodiment of the present invention. FIG. 1 has been reproduced below for convenience of reference.

In a first step 1, the 3D image data of the area to be treated, particularly of the heart chamber to be treated, are recorded. The 3D image data are recorded by way of a method of tomographic 3D imaging such as, for example, X-ray computer tomography, magnetic resonance tomography or 3D ultrasonic techniques. During the recording of the 3D image data, the image data are in each case recorded for the same heart phase for which the electroanatomical 3D mapping data will also be provided later.[7]

[7] Sub. Spec. at p. 7, ll. 13-27 (¶21).



It is of importance to record high-resolution image data of the heart chamber which is electroanatomically measured during the catheter application. Preferably, a contrast medium in association with a test bolus or bolus tracking is therefore used for recording the 3D image data.[8]

In a second step, image data, or at least significant portions of it, are extracted from the recorded 3D image data. The extraction 2 may be performed

[8] Sub. Spec. at p. 7, ll. 29-34 (¶22).

by volume clipping, volume punching or segmenting the 3D image data in order to obtain a 3D surface profile of the heart chamber. The segmentation may represent the surface profile of objects in the superimposed image representation and may be used for the correlation with the 3D mapping data in the correct position and dimension.[9]

According to example embodiments, extraction takes place in the extraction module 11 of the present device 10. This extraction module 11 receives the recorded 3D image data via a corresponding input interface 14. In the same way, the 3D mapping data are supplied to the device 10 via the same or another interface 15, as a rule continuously, during the period of the electrophysiological catheter application.[10]

Segmentation of the heart chamber to be treated can take place in the form of a 2D segmentation in individual layers. One possibility resides in performing a fully automatic segmentation of all layers of the heart chamber obtained by the imaging method. As an alternative, one or more of the layers can also be segmented interactively by an operator and the layers following in each case can be segmented automatically on the basis of the prior knowledge of the layers already segmented. After the segmentation of all individual layers, the 3D surface profile of the heart chamber can then be reconstructed.[11]

The 3D surface profile of the objects, obtained from the extraction, is supplied to the registration module 12 in which the 3D image data are correlated with a 3D mapping data provided in step 3 in the correct position and dimension.

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[9] Sub. Spec. at p. 8, ll. 11 – 31 (¶¶24-26).
[10] Sub. Spec. at p. 9, ll. 26-32 (¶29).
[11] Sub. Spec. at p. 9, ll. 1-14 (¶27).

The 3D mapping data are obtained via a mapping catheter which supplies 3D coordinates of surface points of the heart chamber to be treated via a 6D position sensor integrated into the tip of the catheter.[12]

In the registration step 4 in the registration module 12, the dimensions of the selected 3D image data and of the 3D mapping data are also matched apart from the correlation in the correct position. This is required in order to achieve the most accurate superimposition possible of the 3D image data of the heart chamber or of its surface in the same orientation, scaling and shape with the corresponding visualization of the heart chamber from the 3D mapping data.[13]

According to example embodiments, the registration can take place by visual matching. For this purpose, an operator changes the data visualized until the position, orientation, scaling and/or shape of the heart chamber displayed matches in both representations, i.e. on the basis of the 3D image data and on the basis of the 3D mapping data. The visual matching can take place via a suitable graphical user interface 9. Artificial markers can be used for the registration.[14]

According to example embodiments, global anatomic markers may be used. These distinct points must be identifiable in the 3D image data and are preferably approached with the mapping catheter by using a fluoroscopic imaging technique. The distinct points can then be detected automatically in the 3D image data and the 3D mapping data so that a correlation of these data with the correct position and dimension can be calculated.[15]

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[12] Sub. Spec. at p. 9, line 34 – p. 10, line 8 (¶30).
[13] Sub. Spec. at p. 10, ll. 24-35 (¶32).
[14] Sub. Spec. at p. 11, ll. 1-7 (¶23).
[15] Sub. Spec. at p. 11, ll. 9-18 (¶34).

When the heart chamber to be treated is extracted by way of segmentation, the extracted 3D surface contour of the heart chamber can be automatically matched to the surface contour of the heart chamber obtained by the 3D mapping data. In the case of deviations in the shape of the surface contours obtained from the 3D image data and the 3D mapping data, deforming matching algorithms can be applied to the surface contour from the 3D image data or to the surface contour from the 3D mapping data in order to improve the mutual mapping.[16]

The surface matching can be performed, for example, by reducing or even minimizing point spaces between surface points of the mapping data and surface points of the 3D surface contour extracted from the 3D image data (point-to-point matching). As an alternative, the matching can also be performed by reducing or even minimizing point spaces between surface points of the mapping data and interpolated matching points of the 3D image data (point-to-surface matching).[17]

Since only few electroanatomical 3D mapping data are available at the beginning of the catheter ablation, a multi-stage process of the registration is performed. In this process, a registration by a marker takes place in an initial first stage. The accuracy of the registration is then improved in the course of the process by surface matching in a second step.[18]

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[16] Sub. Spec. at p. 11, line 32 – p. 12, line 9 (¶36).
[17] Sub. Spec. at p. 12, ll. 11-18 (¶37).
[18] Sub. Spec. at p. 12, ll. 20-29 (¶38).

2. AN EXPLANATION OF THE SUBJECT MATTER SET FORTH IN EACH CLAIM ARGUED SEPARATELY REFERRING TO THE SPECIFICATION AND/OR THE DRAWINGS BY REFERENCE CHARACTERS IN ACCORDANCE WITH 37 C.F.R. § 41.37(c)(1)(v).

i. CLAIM 1.

Independent claim 1 is directed to a method for visually supporting an electrophysiology catheter application in the heart.

Independent claim 1 recites "visualizing electroanatomical 3D mapping data, provided during the performance of the catheter application, of an area of the heart to be treated." This reads on the non-limiting example embodiment disclosed, for instance, in page 10, line 24 – page 11, line 30 (¶¶32-35) of the substitute specification filed on February 28, 2006.

Independent claim 1 additionally recites "recording 3D image data of a body region containing the area to be treated with a method of tomographical 3D imaging before the catheter application is carried out, the 3D image data of the body region being high resolution image data." This reads on the non-limiting example embodiment disclosed, for instance, in page 7, lines 13-34 (¶¶21-22) of the substitute specification.

Independent claim 1 also recites "extracting at least significant portions of the area to be treated by segmenting the 3D image data to obtain a 3D surface profile of objects in the area which is to be treated, in order to obtain selected 3D image data." This reads on the non-limiting example embodiment disclosed, for instance, in page 8, line 12 – page 9, line 32 (¶¶24-29) of the substitute specification.

Independent claim 1 also recites "automatically correlating and visualizing the electroanatomical 3D mapping data and the selected 3D image data next to one another in the correct position and dimension using surface matching by at least approximately matching the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data." This reads on the non-limiting example embodiment disclosed, for instance, page 11, line 33 – page 12, line 18 (¶¶33-37) of the substitute specification.

ii. CLAIM 6.

Claim 6 is dependent on claim 1 and, thus, requires all the features discussed above with reference to claim 1.

Claim 6 further provides that "the correlation with the correct position and dimension is effected automatically in a first stage during the performance of the catheter application by way of at least one of distinct anatomical points and artificial markers and is refined by the surface matching in a later second stage, in which the 3D surface profile from the 3D image data is at least approximately matched to a 3D surface profile from the 3D mapping data."

This reads on page 13, ll. 6-23 (¶¶40-41) of the substitute specification.

iii. CLAIM 15.

Independent claim 15 recites "at least one input interface for electro-anatomical 3D mapping data and 3D image data, the 3D image data being high resolution image data." This reads on the non-limiting example embodiment

disclosed, for instance, in page 7, line 13 – page 8, line 17 (¶¶21-24) and FIG. 1 of the substitute specification and drawings.

Independent claim 15 recites "an extraction module, designed to extract at least significant portions of an area to be treated by segmenting the 3D image data to obtain a 3D surface profile of objects in the area which is to be treated to provide selected 3D image data." This reads on the non-limiting example embodiment disclosed, for instance, in page 8, line 12 – page 9, line 32 (¶¶24-29) of the substitute specification and FIG. 1 of the drawings.

Independent claim 15 recites "a registration module, connected to the extraction module, designed for automatic correlation of the electroanatomical 3D mapping data and the selected 3D image data in the correct position and dimension by surface matching the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data." This reads on the non-limiting example embodiment disclosed, for instance, page 11, line 33 – page 12, line 18 (¶¶33-37) of the substitute specification and FIG. 1 of the drawings.

Independent claim 15 recites "a visualization module, connected to the registration module, to provide the 3D mapping data and the selected 3D image data for visualization in the correct position and dimension, next to one another, using at least one display unit." This reads on the non-limiting example embodiment disclosed, for instance, in page 10, line 24 – page 11, line 30 (¶¶32-35) of the substitute specification and FIG. 1 of the drawings.

iv. CLAIM 21.

Claim 21 is dependent on claim 15 and, thus, requires all the features discussed above with reference to claim 15.

Claim 21 further provides that "the registration module is designed for automatic correlation in the correct position with the correct dimension in a multi-stage process, wherein the correlation in the correct position and the correct dimension is effected by way of at least one of distinct anatomatical points and artificial markers in a first stage and is refined by surface matching of the 3D surfaced profile from the 3D image data to a 3D surface profile from the 3D mapping data in a later, second stage."

This reads on page 13, ll. 6-23 (¶¶40-41) of the substitute specification.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL.

A. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIMS 1-3, 9-10, 14-15, 18 AND 22 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE AND HEMLER.[19]

B. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIMS 17, 21 AND 6 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE, HEMLER AND WILLIAMS.[20]

C. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIMS 23 AND 13 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE, HEMLER AND HUGHES.[21]

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[19] Final Office Action, U.S. Appln. No. 10/569,597, U.S. Pat. and Trademark Office, p. 2 (September 16, 2010).
[20] Id. at 5.
[21] Id. at 6.

D. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIM 8 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE, HEMLER AND SCHWEIKARD.[22]

E. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIM 11 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE, HEMLER AND KRISHNAN.[23]

F. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIM 12 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE, HEMLER AND MASSARO.[24]

Claims 1-3, 6, 8-15, 17-18 and 21-23 are being appealed.

Claims 1-3, 8-15, 17-18 and 22-23 rise and fall together.

Claims 6 and 21 rise and fall together.

VII. ARGUMENT.

A. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIMS 1-3, 9-10, 14-15, 18 AND 22 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE AND HEMLER.

Appellants request that the Board reverse the Examiner's rejection of claims 1-3, 9-10, 14-15, 18 and 22 as being unpatentable under 35 U.S.C. § 103(a) unpatentable over Packer in view of Leiper, Rose and Hemler.

1. PRINCIPALS OF LAW.

[22] Id. at 7.
[23] Id.
[24] Id. at 8.

The Examiner bears the initial burden of presenting a *prima facie* case of obviousness in rejecting claims under 35 U.S.C. § 103. *See In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1956, 1958 (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), *viz.*, (1) the scope and content of the prior art; (2) the differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the art. "[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

Furthermore, "'there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness'...[H]owever, the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the would employ." *KSR Int'l Co. v. Telefax Inc.*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)).

2. PACKER, LEIPER, ROSE AND HEMLER FAIL TO DISCLOSE OR SUGGEST AN INTERFACE FOR "ELECTROANATOMICAL 3D MAPPING DATA AND 3D IMAGE DATA," AS RECITED IN CLAIM 15.

FIG. 1 of Packer illustrates a MRI apparatus. Col. 3, lines 51-67 of Packer relate to imaging modality for producing a high resolution model (CT, MRI, ultrasound). Col. 2, lines 14-60 of Packer disclose acquiring image data of the subject anatomy and reconstructing an image which is a high resolution model of the subject anatomy; performing a medical procedure in which the subject anatomy is imaged in real-time by acquiring low resolution images at a high frame rate; registering the high resolution model of the subject anatomy with each acquired low resolution image; and displaying images of the registered high resolution model of the anatomy.

It is alleged in the September 16, 2010 Office Action that FIG. 1, col. 2, lines 14-60, col. 3, lines 51-67 and col. 5, lines 45-62 of Packer teach an interface for "electroanatomical 3D mapping data and 3D image data," as recited in independent claim 15. However, as demonstrated above, Packer acquires low resolution images, not 3D images.

In addition, the Examiner provides a generic statement, on page 2 of the Office Action, that "Packer discloses a system that perform [sic] an imaging method therefore the system must have at least one input interface for electroanatomical 3D mapping data and 3D image data." However, as demonstrated above, Packer acquires low resolution images, not 3D images.

Moreover, the Examiner provides that Packer "must" have an interface for 3D mapping and image data. However, in establishing that an element is inherent in a reference, the missing element must be necessarily present in the apparatus described in the reference(s) such that the presence of these elements would be recognizable by persons of ordinary skill. *In re Robertson*, 169 F.3d 743,

745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). The Examiner has not established that an interface for 3D mapping and image data is inherent to the disclosure of Packer because another interface can be used. For example, Packer even goes as far to disclose an interface for low resolution images, but does not disclose an interface for 3D mapping data and 3D image data.

Leiper, Rose and Hemler fail to cure the deficiencies of Packer described above.

Therefore, Packer, Leiper, Rose and Hemler fail to disclose or suggest an interface for "electroanatomical 3D mapping data and 3D image data," as recited in claim 15.

3. PACKER, LEIPER, ROSE AND HEMLER FAIL TO DISCLOSE OR SUGGEST "ELECTROANATOMICAL 3D MAPPING DATA AND 3D IMAGE DATA," AS RECITED IN CLAIM 15.

FIG. 8 of Packer illustrates a flowchart for producing a high resolution, large field of view images in real-time on the display, "overlaying devices on image (242)" and an arrow from block 242 to the beginning. Col. 9, line 21 – col. 10, line 36, describes the flowchart (FIG. 8), without referring to *any* electrophysiological data. The cited text passages or figures do not describe how electrophysiological data are merged with the anatomic model.

The Examiner relies on Packer to teach the "registration module," of claim 15. However, Packer fails to disclose or suggest "a registration module ... for automatic correlation of the electroanatomical 3D mapping data and the selected 3D image data." In other words, Packer discloses a registration module designed

for correlation of high resolution 2D, 3D or 4D model data with acquired low resolution ultrasonic image data. The low resolution image data are not electroanatomical 3D mapping data.

Leiper, Rose and Hemler fail to cure the deficiencies of Packer described above.

Therefore, Packer, Leiper, Rose and Hemler fail to disclose or suggest "a registration module ... for automatic correlation of the electroanatomical 3D mapping data and the selected 3D image data," as recited in claim 15.

4. PACKER, LEIPER, ROSE AND HEMLER FAIL TO DISCLOSE OR SUGGEST "AUTOMATIC CORRELATION," AS RECITED IN CLAIM 15.

Packer in col. 12, line 35 – col. 13, line 15 discloses that the location of the electrodes is registered manually with the high resolution image. "This is done by aiming the ultrasonic transducer 30 at each electrode 268, placing a cursor on an electrode pictured in the image, and typing in the electrode number."[25]

Without this manual registration, it would not be possible to assign the measured activation in form of a color modulation of the appropriate pixel. Further, sensing electrical signals in Packer is not "3D mapping" as claimed, since the electrical signals produced by the electrodes of Packer (268, FIGS. 9-10) indicate the relative timing of the signals during a cardiac cycle. As such, they cannot be regarded as electroanatomical 3D mapping data, but only as voltage over time signals.

[25] Col. 12, lines 52-61 of Packer.

Additionally, the arrow from block 242 to the beginning (FIG. 8) does not mean that the high resolution model with the overlaid electrophysiological data is input to the registration procedure with the real-time image.

The arrow means that the displayed image is continuously updated, i.e. a new real-time image is registered with a newly selected high resolution image (according to the ECG phase) and this image is overlaid again with the electrophysiological data by modulating the pixel color. Therefore, Packer does not disclose an "automatic registration" of the 3D image data and electroanatomical 3D mapping data.

Leiper, Rose and Hemler fail to cure the deficiencies of Packer described above.

Therefore, Packer, Leiper, Rose and Hemler fail to disclose or suggest "automatic correlation," as recited in claim 15.

5. A *PRIMA FACIE* CASE OF OBVIOUSNESS HAS NOT BEEN ESTABLISHED BECAUSE THE REJECTION OF CLAIMS 1-3, 9-10, 14-15, 18 AND 22 OVER PACKER IN VIEW OF LEIPER, ROSE AND HEMLER LACKS THE REQUISITE ARTICULATED REASONING WITH SOME RATIONAL UNDERPINNING TO SUPPORT THE LEGAL CONCLUSION OF OBVIOUSNESS.

It is further alleged in the Office Action at page 3 that col. 6, lines 14-45 and col. 7, lines 7-23 of Packer disclose "an extraction module, designed to extract at least significant portions of an area to be treated by segmenting the 3D image data to obtain **a 3D surface profile**," as recited in independent claim 15. (Emphasis added.)

However, the cited sections of Packer are directed to the process of rendering acquired 3D surfaces on a 2D display. Further, these sections of Packer are directed to processing the acquired 3D image data into a 4D model from which 3D heart wall surfaces can be rendered. This process of rendering acquired 3d surfaces involves segmenting of the heart walls and tiling of the surfaces of the segmented heart wall images. However, no "3D surface profile" is extracted. Packer fails to teach or even suggest "a 3D surface profile," as recited in independent claim 1.

Moreover, the Examiner admits that Packer does not explicitly teach "3D surface profile," as required by claim 15, and relies on the teachings of Rose to overcome the noted deficiencies of Packer.

Particularly, the Examiner alleges that paragraphs [0005-0007] of Rose teach "surface matching the 3D surface profile," as recited in independent claim 15.

Rose is directed to a non-contact surface profiling method using light. Rose focuses primarily upon road surfaces. However, as per Rose, the discussion applies equally to any surface intended for vehicular traffic. According to Rose, these surfaces include, but are not limited to, highways, roads, ramps, parking, and service areas for ground vehicles (trucks, cars, busses, etc.), runways, taxiways, parking aprons, and hangar floors for aircraft, and tracks and roadbeds for railroads. The terms "road" and "road surface," as used herein, refer specifically to "a road" and "a surface of a road," respectively, and refer generally to "a way or course for ground, air, or rail vehicles" and "a surface of a way or

course," respectively. The sections of Rose cited by the Examiner are reproduced below.

> **[0005]** In the industry, road condition is measured by profiling. Profiling is the obtaining of a profile or series of profiles of the road surface. A profile is substantially a cross-sectional view of the surface of the road. A profile depicts the contours of the road, thereby demonstrating the form, wear, and irregularities of the road surface.
> **[0006]** A transverse profile is a cross-sectional view of the road surface or a portion thereof taken substantially perpendicular to the direction of travel. A transverse profile may be used to depict rutting, potholes, scaling, chipping, and edge damage of the road surface over time.
> **[0007]** A longitudinal profile is a cross-sectional view taken substantially in the direction of travel. A longitudinal profile may be used to depict the grade, waviness, and roughness of the road surface. Longitudinal profiles may be used to monitor the wear of the road surface over time to facilitate maintenance planning.
>
> (Emphasis added.)

Rose fails to teach or fairly suggest any "surface profiling" that is concerned with anatomy of living organisms. Rose is directed to surface-profiling of road surfaces.

On pages 3-4 of the Office Action dated September 16, 2010, the Examiner states that it would have been obvious

> to modify Packer to have a system that display multiple images side by side one computer monitor or on multiple computer monitors, surface profile, surface matching as taught by Leiper, Rose and Hemler because it would be easier for comparing and analyzing images[.]

According to *KSR Int'l Co. v. Teleflex Inc.*, in order for Packer in view of Leiper, Rose and Hemler to forbid issuance of claim 15, the differences between claim 15 and the prior art must be such that the claimed subject matter as a whole would have been obvious to a person having ordinary skill in the relevant

art at the time the invention was made.[26] Moreover, rejections on obviousness grounds must be accompanied by some "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness[;]" obviousness rejections cannot be sustained by mere conclusory statements.[27]

There must be "an apparent reason to combine the known elements in the fashion claimed by the patent at issue." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (April 30, 2007) (emphasis added.)

The reasons provided on pages 3-4 of the Office Action dated September 16, 2010 do not provide a rational underpinning as to why a person having ordinary skill in the art at the time of the invention would have modified the teachings of Packer with Leiper, Rose and Hemler to meet the limitations of claim 15.

More specifically, the Examiner has not stated how or why a combination of Packer with Leiper, Rose and Hemler would result in the method set forth in claim 1. The Examiner has provided no reason how the combination would produce a benefit. "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

Indeed, at least the "3D surface profile" and "surface matching," of claim 15, is not disclosed or suggested by the cited art, and there is no suggestion that this was known to one of ordinary skill in the art at the time of the invention.

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[26] 550 U.S. 398, 406 (2007).
[27] *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR*, 550 U.S. at 418.

Because the Examiner has not provided the requisite rational underpinning to combine Packer, Leiper, Rose and Hemler, a proper *prima facie* case of obviousness has not been established. The extensive amount of modification needed is suggested nowhere in the cited references or by the Examiner, and is born from use of impermissible hindsight reconstruction in view of the Appellants' Specification and reading of the claims. (See, for example, *Ex parte* Kobayashi, Appeal 2009-000884, Application 10/031,282).

5. CONCLUSION.

As described above, Packer, Leiper, Rose and Hemler fail to disclose or suggest "electroanatomical 3D mapping data and 3D image data" and "electroanatomical 3D mapping data and 3D image data," as recited in claim 15. Moreover, the Examiner has failed to establish a *prima facie* case of obviousness. Therefore, Packer, Leiper, Rose and Hemler fail to render claim 15 obvious.

Claim 1 is a separate independent claim from claim 15, wherein claim 1 contains its own individual limitations. Each independent claim should be interpreted solely based upon limitations set forth therein. However, claim 1 is patentable for at least reasons somewhat similar to those set forth above regarding claim 15. Claims 2-3, 9-10 and 14 are patentable based at least on their dependency on claim 1. Claims 18 and 22 are patentable at least by virtue of its dependency on claim 15.

Therefore, Appellants respectfully request that the Board withdraw the rejections of claims 1-3, 9-10, 14-15, 18 and 22 under 35 U.S.C. § 103.

B. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIMS 17, 21 AND 6 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE, HEMLER AND WILLIAMS.

Appellants request that the Board reverse the Examiner's rejection of claims 17, 21 and 6 as being unpatentable under 35 U.S.C. § 103(a) over Packer in view of Leiper, Rose, Hemler and Williams.

The Examiner takes the position that claims 17, 21 and 6 are unpatentable over Packer in view of Leiper, Rose, Hemler and Williams. Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

Hemler discloses a system for combining CT and MR images. Anatomical landmarks, such as bones, are segmented semi-automatically in both images, a transformation is determined and a registration measure is computed.

Williams discloses a registration method wherein fiducial markers [0037, 0038] are touched by a position sensor and the position of the markers with respect to the previously acquired image is ascertained by a computer in which the previously acquired image has been loaded. The touching of several markers enables image registration.

However, none of Hemler and Williams teach or fairly suggest the method of claim 6 comprising "correlation .. in a first stage during the performance of the catheter application ... refined by the surface matching in a later second stage." Namely, none of Packer, Leiper, Rose, Hemler and Williams, alone or in combination, teach or fairly any multi-stage process as required by claim 6.

Accordingly, any combination of Packer, Leiper, Rose, Hemler and Williams would fail to render the limitations of claim 6 *prima facie* obvious.

Furthermore, for at least the reasons above, a *prima facie* case of obviousness cannot be established with regard to independent claim 1. Consequently, a *prima facie* case of obviousness cannot be established with regard to claim 6, at least by virtue of its dependency from claim 1. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

Claims 17 and 21 are patentable for at least somewhat similar reasons and based on their dependency on claim 15.

Appellants request the Board overturn the rejection of claims 17, 21 and 6under 35 U.S.C. § 103(a).

C. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIMS 23 AND 13 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE, HEMLER AND HUGHES.

The Examiner takes the position that claims 23 and 13 are unpatentable over Packer in view of Leiper, Rose, Hemler and Hughes. Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

The above-discussed deficiencies of Packer, Leiper, Rose and Hemler are also applicable to this rejection. Furthermore, the additional teachings of Hughes fail to remedy the deficiencies of Packer, Leiper, Rose and Hemler.

For at least the reasons above, a *prima facie* case of obviousness cannot be established with regard to claims 1 and 15. Consequently, a *prima facie* case of obviousness cannot be established with regard to claims 13 and 23, at least by virtue of their dependency from claim 1 or 15. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

D. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIM 8 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE, HEMLER AND SCHWEIKARD.

The Examiner takes the position that claim 8 is unpatentable over Packer in view of Leiper, Rose, Hemler and Schweikard. Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

The above-discussed deficiencies of Packer, Leiper, Rose and Hemler are also applicable to this rejection. Furthermore, the additional teachings of Schweikard fail to remedy the deficiencies of Packer, Leiper, Rose and Hemler.

For at least the reasons above, a *prima facie* case of obviousness cannot be established with regard to claim 1. Consequently, a *prima facie* case of obviousness cannot be established with regard to claim 8, at least by virtue of its dependency from claim 1. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

E. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIM 11 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE, HEMLER AND KRISHNAN.

The Examiner takes the position that claim 11 is unpatentable over Packer in view of Leiper, Rose, Hemler and Krishnan. Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

The above-discussed deficiencies of Packer, Leiper, Rose and Hemler are also applicable to this rejection. Furthermore, the additional teachings of Krishnan fail to remedy the deficiencies of Packer, Leiper, Rose and Hemler.

For at least the reasons above, a *prima facie* case of obviousness cannot be established with regard to claim 1. Consequently, a *prima facie* case of obviousness cannot be established with regard to claim 11, at least by virtue of its dependency from claim 1. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

F. APPELLANTS SEEK THE BOARD'S REVIEW OF THE REJECTION OF CLAIM 12 UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER PACKER IN VIEW OF LEIPER, ROSE, HEMLER AND MASSARO.

The Examiner takes the position that claim 12 is unpatentable over Packer in view of Leiper, Rose, Hemler and Massaro. Appellants respectfully disagree with the Examiner's position for the reasons expressed below.

The above-discussed deficiencies of Packer, Leiper, Rose and Hemler are also applicable to this rejection. Furthermore, the additional teachings of Massaro fail to remedy the deficiencies of Packer, Leiper, Rose and Hemler.

For at least the reasons above, a *prima facie* case of obviousness cannot be established with regard to claim 1. Consequently, a *prima facie* case of obviousness cannot be established with regard to claim 12, at least by virtue of its dependency from claim 1. Accordingly, Appellants respectfully request the Board to reverse the Examiner's rejection.

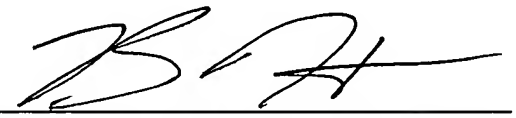
VIII. CONCLUSION.

In light of the foregoing arguments, Appellants respectfully request the Board to reverse the Examiner's rejection of claims 1-3, 6, 8-15, 17-18 and 21-23.

The Commissioner is authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, PLC

By 

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IX. CLAIMS APPENDIX.

Claims on Appeal:

1. (Previously Presented) A method for visually supporting an electrophysiology catheter application in the heart, comprising:

visualizing electroanatomical 3D mapping data, provided during the performance of the catheter application, of an area of the heart to be treated;

recording 3D image data of a body region containing the area to be treated with a method of tomographical 3D imaging before the catheter application is carried out, the 3D image data of the body region being high resolution image data;

extracting at least significant portions of the area to be treated by segmenting the 3D image data to obtain a 3D surface profile of objects in the area which is to be treated, in order to obtain selected 3D image data; and

automatically correlating and visualizing the electroanatomical 3D mapping data and the selected 3D image data next to one another in the correct position and dimension using surface matching by at least approximately matching the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data.

2. (Previously Presented) The method as claimed in claim 1, wherein the 3D image data of the body region are recorded with a method of at least one of X-ray computer tomography and magnetic resonance tomography.

3. (Previously Presented) The method as claimed in claim 1, wherein the 3D image data of the body region are recorded by use of a 3D ultrasonic method.

4. (Cancelled)

5. (Cancelled)

6. (Previously Presented) The method as claimed in claim 1, wherein the correlation with the correct position and dimension is effected automatically in a first stage during the performance of the catheter application by way of at least one of distinct anatomical points and artificial markers and is refined by the surface matching in a later second stage, in which the 3D surface profile from the 3D image data is at least approximately matched to a 3D surface profile from the 3D mapping data.

7. (Cancelled)

8. (Previously Presented) The method as claimed in claim 1, wherein the correlation in the correct position and dimension is made automatically using artificial markers which are attached to the patient's thorax before the 3D image data are recorded, and are identifiable both in the 3D image data and in the 3D mapping data.

9. (Previously Presented) The method as claimed in claim 1, wherein the correlation in the correct position and dimension is made automatically using distinctive anatomical points which can be identified both in the 3D image data and in the 3D mapping data.

10. (Previously Presented) The method as claimed in claim 1, wherein the selected 3D image data are visualized via a volume rendering technique.

11. (Previously Presented) The method as claimed in claim 10, wherein the selected 3D image data are visualized using an adjustable volume rendering transfer function.

12. (Previously Presented) The method as claimed in claim 1, wherein the selected 3D image data are visualized as polygonal grid.

13. (Previously Presented) The method as claimed in claim 1, wherein the two visualizations are linked to one another such that when a user rotates, moves or scales one of the visualizations the other visualization is simultaneously subjected to the same rotation, movement or scaling.

14. (Previously Presented) The method as claimed in claim 1, wherein registration between the 3D image data and the 3D mapping data prompts a representation, contained in the 3D mapping data, of at least some of the catheter to be shown in the visualization of the selected 3D image data in real time.

15. (Previously Presented) A device comprising:

at least one input interface for electroanatomical 3D mapping data and 3D image data, the 3D image data being high resolution image data;

an extraction module, designed to extract at least significant portions of an area to be treated by segmenting the 3D image data to obtain a 3D surface profile of objects in the area which is to be treated to provide selected 3D image data;

a registration module, connected to the extraction module, designed for automatic correlation of the electroanatomical 3D mapping data and the selected 3D image data in the correct position and dimension by surface matching the 3D surface profile from the 3D image data to a 3D surface profile from the 3D mapping data; and

a visualization module, connected to the registration module, to provide the 3D mapping data and the selected 3D image data for visualization in the correct position and dimension, next to one another, using at least one display unit.

16. (Cancelled)

17. (Previously Presented) The device as claimed in claim 15, wherein the registration module is designed for the automatic correlation in the correct position and dimension using artificial markers, identifiable both in the 3D image data and in the 3D mapping data.

18. (Previously Presented) The device as claimed in claim 15, wherein the registration module is designed for the automatic correlation in the correct position and dimension using distinctive anatomical points which are identifiable both in the 3D image data and in the 3D mapping data.

19. (Cancelled)

20. (Cancelled)

21. (Previously Presented) The device as claimed in claim 15, wherein the registration module is designed for automatic correlation in the correct position with the correct dimension in a multi-stage process, wherein the correlation in the correct position and the correct dimension is effected by way of at least one of distinct anatomatical points and artificial markers in a first stage and is refined by surface matching of the 3D surfaced profile from the 3D image data to a 3D surface profile from the 3D mapping data in a later, second stage.

22. (Previously Presented) The device as claimed in claim 15, wherein the visualization module is designed for visualizing a part of a catheter used within the representation of the selected 3D image data in real time.

23. (Previously Presented) The device as claimed in claim 15, wherein the visualization module is designed so that when a user rotates, moves or scales one

of the visualizations the other visualization is simultaneously subjected to the same rotation, movement or scaling.

24. – 29. (Cancelled)

X. EVIDENCE APPENDIX.

None.

XI. RELATED PROCEEDINGS APPENDIX.

None.

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